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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,580	03/29/2007	Shyam S. Mohapatra	USF.208TCXC1	6999

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
07/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,580	MOHAPATRA ET AL.	
	Examiner	Art Unit	
	Richard Schnizer	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/14/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/10 has been entered.

Claims 15-22, 24-26, and 32-43 were canceled and claims 44 and 45 were added.

Claims 12-14, 44, and 45 are pending and under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-14, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over McSwiggen et al (US Patent 5,693,532) in view of Tuschl et al (US 20040259247 A1), and Chen et al (US 20040242518).

McSwiggen taught methods of inhibiting the replication of RSV in vivo in infected humans through use of specific ribozymes targeted to RSV mRNA for treatment of diseases in man and other animals. In one embodiment, the ribozymes are targeted to NS1 transcripts. See columns 2-3, for example (e.g. paragraph bridging columns 2 and 3). Preferred administration is by aerosol inhalation which would provide delivery to the airways (see column 9, lines 8-16). The ribozymes can be expressed from vectors (column 5, lines 10-12 and 27-52) under the control of eukaryotic pol I, pol II, or pol III promoters (column 9, lines 17-27).

McSwiggen did not teach administration of siRNA encoding vectors, or administration to a subject not suffering from RSV infection (instant claim 14).

Tuschl taught methods and materials for making and using short, double stranded interfering RNAs (siRNAs) against virtually any known gene for both research and clinical use. It is said the target gene to which the RNA molecule of the invention is directed may be a viral gene associated with a pathological condition (paragraph 30). The siRNAs consist of sense and antisense strands of between 19 and 25 nucleotides in length, wherein the antisense strand is complementary to a target gene (cols. 1-3). Tuschl taught and/or suggested both in vitro transfection and in vivo delivery of siRNAs for therapeutic purposes (pages 3-4, and see examples). Thus, Tuschl provided a general blueprint for the design, synthesis, and application of short interfering RNAs.

Tuschl also directly compared and contrast ribozyme and RNAi technologies, stating at paragraph 148 that "...siRNAs are extraordinarily powerful reagents for mediating gene silencing and that siRNAs are effective at concentrations that are

several orders of magnitude below the concentrations applied in conventional antisense or ribozyme gene targeting experiments."

Chen taught the use of siRNA expression vectors to inhibit viral infection in human lungs. Chen exemplified the use of siRNA expression vectors to prophylactically inhibit influenza infection in mouse lung. DNA expression vectors encoding siRNA directed to influenza virus transcripts were administered to mice, followed by administration of PR8 influenza virus. Fig. 26 shows that lower virus titers were observed when mice were given plasmid DNA that expressed either NP-1496a shRNA or PB1-2257 shRNA. The virus titers were more significantly decreased when mice were given both influenza-specific plasmid DNAs together, one expressing NP-1496a shRNA and the other expressing PB1-2257 shRNA. These results show that shRNA expressed from DNA vectors can be processed into siRNA to inhibit influenza virus production in vivo. See paragraphs 58, 185, 214, and Example 14 at paragraphs 429-437. Chen also taught that viral vectors could be used to delivery siRNAs (paragraphs 9, 55, 91, 161-164, 252. Chen envisioned delivery to humans (paragraphs 88, 156, and 248).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute siRNAs directed against RSV N1 for the N1-directed ribozymes of McSwiggen in order to inhibit the expression of an RSV mRNA, and to use the vectors of Chen to express them in the human lung in vivo. One of skill would have been motivated to do so because Tuschl taught that siRNAs are in general significantly more potent than ribozymes. In view of the fact that Chen demonstrated that siRNA

expression vectors targeting influenza virus could be delivered to the mouse lung in vivo and reduce the titre of the target virus, one of skill would have reasonably expected that siRNAs targeted to RSV could be successfully delivered and expressed in vivo as well, and so would have had a reasonable expectation of success.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the siRNA expression vectors to a subject not suffering from RSV infection in order to prevent infection, and would have had a reasonable expectation of success in view of the results of Chen who showed that expression of anti-influenza siRNAs prior to infection decreased the titer of subsequently infecting influenza virus.

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official central fax

number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Richard Schnizer/
Primary Examiner, Art Unit 1635